US ERA ARCHIVE DOCUMENT

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

To:

PM 16

Subject: 002724-314

Safrotin 4 EC

Zoecon Corp.

Palo Alto, CA 94304

In TSS: 08/23/84

Assign: 09/06/84 Due: 09/07/84

AC: 345

Accn: 254456

RN: 128137

OLTS: 38

Formulation: Propetamphos.....50.06%

### BACKGROUND

in the existing rormulation Registrant wishes to replace been rumored to be a mutagen and it has been indicated that the state of California now has reservations about accepting pesticides containing this solvent.

## **USES**

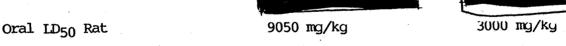
## Restricted Use Pesticide

Domestic and commercial use indoors as an 0.5-1.0% oil or water carrier residual spray to control crawling insect pests.

# SUBMITTED DATA

Accession number 254456.

Background from 1.



17% Mortality 4 Hr. Inhalation of No mortality Concentrated Vapors

Trace Skin Irritation, Rabbit None

Minor Injury Eye-Rabbit Trace

3500 mg/kg 16500 mg/kg Dermal LD50

- Statements only, no actual data derived from testing or complete test reports.
  - A. Oral-Kidney injury noted in dead animals. A 10 mg/kg daily dose gave no harmful effects in a 2 yr. study
  - B. Dermal-Same as reported in 1. above.
  - C. Inhalation— Saturated atmosphere killed 6/6 in a 4 hour exposure study (differs from chart in 1. above).
  - D. Skin Irritation— 141 human volunteers treated. 5 showed sensitizing reactions. No acute dermal irritation resulted.
  - E. Eye Irritation- 0.5 ml gave only "moderate" irritation. This also differs from the previous
- 3. Acute Dermal Toxicity. Sandoz Inc. East Hanover, NJ 07936.

  Report No. T-1-11/4/83. Safrotin 50 EC 63. Project T-1961.

  5 M and 5 F NZ albino rabbits per dose individually housed. All sites clipped. Abrasion not reported, sites presumed intact. Topical application, exposure period not reported. 15 day observation period. Toxic signs included diarrhea, ataxia, tremors, etc. Death was delayed, most frequently occuring on day 3. Necropsies not reported. Results:

| Dose, mg/kg | Percent Mortality: | <u>Males</u> | <u>Females</u> |
|-------------|--------------------|--------------|----------------|
| 315         |                    | 0            | 0              |
| 353         |                    | 100          | 0 *            |
| 398         | * *                | 100<br>100   | 0<br>20        |
| 500         |                    | 100          | 20             |
| 628         |                    | TOO          | 20             |

Supplementary Data- There are many experimental details missing. The results are insufficient to determine the actual  ${\rm LD}_{50}\, \cdot$ 

4. Eye Irritation. Sandoz Ltd. Basel Switzerland. AGRO DOK CBK 1.5555/82. Safrotin 50 EC 63. 9 albino rabbits, individually housed. 0.1 ml. product per eye. 6 unwashed and 3 washed eyes. Results:

Corneal Opacity- None Iritis- None

Conj. Irritation- Occured in 1/6 uw and 0/3 w. All clear by day 2.

Supplementary Data- No individual reports.

5. Primary Dermal Irritation. Sandoz Ltd., Basel Switzerland.

[AGRO DOK CBK I.5554/82. Safrotin 50 EC 63

3 Male albino rabbits, individually housed. 0.5 g per site. All sites shaved. 4 hour occluded exposure. PDIS = 0.0.

#### CONCLUSIONS

- 1. All of the submitted studies are supplementary data.
- 2. The company should confirm that Safrotin 50 EC 63 as tested was indeed the formulation with and and not be determined from the submitted data.
- 3. If the formulation in the submitted supplementary data is indeed the formulation with the submitted supplementary data is indeed the alternate formulation providing that the submission of a complete acute tox. series be made a condition of registration. It should be noted that is a compound very closely related to which has been rumored to have adverse chronic effects resulting in regulatory actions in California. TSS recommends, therefore, that the PM team consult with Toxicology Branch, HED prior to the approval of the alternate formulation.

Phil Hutton TSS/IRB